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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,675	01/29/2001	Edward L. Squires	XY-EQUINE3-U	3456
33549 7590 07/03/2008 SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521				
EXAMINER				
MYERS, CARLA J				
ART UNIT		PAPER NUMBER		
1634				
NOTIFICATION DATE		DELIVERY MODE		
07/03/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

09/744,675

**Applicant(s)**

SQUIRES ET AL.

**Examiner**

Carla Myers

**Art Unit**

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 138-145 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 138-145 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date: \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This action is in response to the amendment filed April 2, 2008. Applicant's arguments and amendments to the claims have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn.

In particular, the rejection of claims 138-145 under 35 USC 112, first paragraph (new matter) has been obviated by the amendment to the claims to delete the claim language of "at success levels not statistically different as compared to an unsorted equine artificial insemination dosage containing about the same number of sperm cells."

This action is made Final.

2. Claims 138-145 are pending and have been examined herein.

### **Terminal Disclaimer**

3. The terminal disclaimer filed on April 2, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 7,195,920 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### **Maintained Rejections**

#### **Claim Rejections - 35 USC § 103**

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 138-140, and 142-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens (U.S. Patent No. 5,985,216) in view of Wilhelm (Cryobiology (1996) 33:320-329) and further in view of Rath (Theriogenology. April 1997, 795-800; cited in the IDS) .

Rens teaches a method of sex-sorting sperm using high speed flow cytometry. In the method of Rens (see columns 4-6), a sample of sperm is obtained from a male mammal, the sperm is stained with Hoechst 33342 dye in order to distinguish between viable and nonviable sperm (column 5, lines 4-10), the sperm are sorted in a high speed flow cytometer using a nozzle that forms a stable droplet containing each individual sperm cell (column 2, lines 23-32), the sperm are sorted according to their sex characteristics and isolated populations of X- and Y-chromosome bearing sperm are collected. Importantly, Rens (col. 5) discloses modifying the MoFlo® high speed cell

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sorter to include a new elliptical nozzle capable of more accurately orienting sperm for accurate sorting. Rens teaches use of the modified MoFlo® sorter using sampling rates of 500 sperm/second and 2000 sperm/second (column 6). Rens teaches that the modified MoFlo® sorter also allowed for sample rates up to at least 15,000 sperm/sec (column 4, lines 29-31). Rens (col. 2) teaches that the high speed flow cytometry apparatus disclosed therein provides for improved accuracy and efficiency of sorting, as compared to prior art flow cytometers. Rens (col. 2) also teaches that it is desirable to use high speed cell sorters to maximize the number of sorted sperm per unit time. For example, Rens (col. 4) discuss the requirement to use large quantities of sperm for artificial insemination and states that by using the high speed cell sorter equipped with the nozzle disclosed therein, the yield of sex sorted sperm cells can be increased at least 10 fold, making artificial insemination with sexed semen a more feasible option. Rens (col. 7) also exemplifies a method wherein a total of 50 million X and Y bovine sperm were sorted in a 7 hour period using the modified MoFlo® sorter equipped with the new elliptical nozzle. Rens further exemplifies using the sorting method to sex-sort rabbit, bull, mouse and human sperm (columns 4-7) and states that the sorting method can be used with any mammalian sperm (column 4, lines 38-42). Rens does not specifically teach applying the sorting method to equine sperm.

However, Wilhelm (page 321) teaches using equine sperm for artificial insemination methods and teaches methods for the effective cryopreservation of equine sperm.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Rens to the sorting of equine sperm in order to have provided an effective means for distinguishing between and collecting populations of X- and Y-chromosome bearing sperm useful for artificially inseminating equine. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the modified MoFlo sorter equipped with the new nozzle of Rens to sort equine sperm at very high sort rates, including sorting rates that result in the collection of 900 viable sperm / second, in order to have allowed for the faster sorting of sperm so as to have provided adequate quantities of sex-sorted samples that could be used for the insemination process. As discussed in MPEP 2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Further, It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also *Merck & Co. v. Biocrraft Labs. Inc.*, 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious). In the present situation, Rens provides the motivation to increase sort speeds to at least that required to achieve the collection of 900 viable sperm/sec and the means for achieving this result (i.e., the modified MoFlo® high speed sorter including the elliptical nozzle of Rens). Thereby, modification of the

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method of Rens so as to have sorted equine sperm at rates that achieve the collection of 900 viable sperm/second would have been obvious to one of ordinary skill in the art and well within the skill of the art at the time the invention was made.

Secondly, Rens does not specify the solution into which the sperm cells are collected and thereby does not teach collecting the sorted sperm in a skim milk solution.

However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Additionally, Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326).

Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender

of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

Regarding the recitation in the claims at step (j), it is considered to be a property of the artificial insemination sample that is obtained using the modified method of Rens in which the equine sperm is collected into a media containing egg yolk and skim milk that the sample contains sperm cells that are capable of fertilizing at least one equine egg within a female equine.

With respect to claim 140, the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk. Furthermore, it would have been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have provided the most effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claim 143, Rens does not specify the pressure used to operate the high speed cell sorter. However, methods for sorting equine sperm using high speed cell sorters were well known in the art at the time the invention was made. To determine the optimum conditions for performing the sorting of sperm, including the sorting rates and pressure of the cell sorter is considered to be well within the skill of the art. As discussed in MPEP 2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).



With respect to claims 144 and 145, Rens teaches that 4 to 5 million sorted sperm were used to inseminate dairy cows, but does not teach the quantity and volume of sperm to be used for equine artificial insemination. Additionally, Rath (page 796) teaches the use of 0.2 million sorted porcine spermatozoa per oviduct and teaches resuspending sorted porcine sperm in a solution having a volume of 0.2 ml. Rath teaches that approximately  $3.5$  to  $4 \times 10^5$  sperm cells were sorted into each tube. Since the parameters which effect artificial insemination of equine were known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the art and well within the skill of the art to have selected an optimum quantity of sperm, wherein said quantity would be less than 25 million and to have selected the optimum volume for the artificial insemination sample, so as to have provided the most effective sample for inseminating equine while keeping the number of sperm to be used for insemination at the lowest possible number given the constraints on how many sperm could be sorted per day and the cost of sorting. Additionally, the ordinary artisan would have recognized that the quantity of sperm and the volume of the sperm sample could be modified in order to have provided the most appropriate sperm sample depending on how the sample would be used – i.e., depending on the amount of sperm present in the original sample, whether the samples would be frozen prior to use, the number of samples to be used for insemination, and the type of insemination technique. Accordingly, to have generated sorted sperm samples containing less than 5 or 25 million sperm or to have generated sorted sperm samples in a volume of .2 or 1 ml would have been obvious to one of ordinary skill in the art because the ordinary artisan

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would have recognized that the quantity of sperm and the volume of sample should be varied depending on how the sperm sample was to be further processed and / or used.

5. Claim 141 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Wilhelm and Rath and further in view of Catt (cited in the IDS of January 29, 2001).

The teachings of Rens, Wilhelm and Rath are presented above. The combined references do not teach establishing a sheath fluid which contains a HEPES buffered medium.

However, Catt teaches that semen may be diluted in a HEPES-buffered SOF (synthetic oviduct fluid) medium and that such a fluid is suitable for maintaining the viability of spermatozoa (see, e.g., page 252 and 257). Catt also teaches that it is beneficial to sort into a medium containing a cushioning of seminal plasma to increase the viability and motility of sperm. Further, Wilhelm (page 321) does teach the use of a HEPES-buffered medium for extending equine sperm.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens in view of Wilhelm so as to have used a HEPES-buffered medium for establishing a sheath fluid. To have used a buffer well known to be effective for diluting and extending sperm as a sheath fluid would have been obvious to one of ordinary skill in the art. Thereby, it would have been obvious to have used a HEPES-buffered medium as the sheath fluid because Catt teaches that this is a suitable dilution medium for sperm this would have achieved the benefit of ensuring the viability and motility of the sperm.

**RESPONSE TO ARGUMENTS / REMARKS**

6. In the response, Applicants state that the rejection cites Rens as teaching a MoFlo® high speed cell sorter equipped with an elliptical nozzle. The response further states that "Applicant believes the subject matter of Rens '216 MoFlo® flow cytometers is disqualified pursuant to 35 U.S.C. 103(c)" because it is the result of a joint research agreement. In the reply, Applicants filed a statement, signed by the attorney of record, indicating that the MoFlo® high speed cell sorter described in the '216 Rens patent and the present patent application were made by or on behalf of parties subject to a joint research agreement that was in effect on or before the date the claimed invention was made. In the reply, the specification was also been amended to indicate that the present invention is the result of a joint research agreement between Colorado State University through its agent Colorado State University Research Foundation and Cytomation Inc.

These arguments, the attorney's statements regarding the joint research agreement and the amendments to the specification have been fully considered but are not effective to overcome the present grounds of rejection. The present rejection is not based on the MoFlo® high speed cell sorter alone. Rather, the rejection is based on the teachings of Rens of a method of sorting cells using a MoFlo® high speed cell sorter modified to include an elliptical nozzle that allows for higher sorting rates and efficiencies. The Rens '216 patent which discloses high speed cell sorters modified to include a new elliptical nozzle and which claims the elliptical nozzle was assigned to the United States of America. There is no evidence of record to indicate that the subject matter of the Rens '216 patent (i.e., a high speed cell sorter, and particularly the

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MoFlo® high speed cell sorter, modified to include an elliptical nozzle) and the presently claimed invention were made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made. That is, a showing of a joint research agreement between Cytomation and the Colorado State University through its agent Colorado State University Research Foundation is not sufficient to overcome the present rejection over the Rens patent because the Rens patent is not assigned to Cytomation and the rejection is not based only on Cytomation's MoFlo® high speed cell sorter, but rather is based on the complete teachings of Rens of a high speed sorter, and particularly the MoFlo® high speed cell sorter, modified to include an elliptical nozzle.

As set forth in MPEP 706.02(I)(2):

Subject matter which is developed by another person which qualifies as prior art only under 35 U.S.C. 102(e), (f) or (g) may be used as prior art under 35 U.S.C. 103 against a claimed invention unless the entire rights to the subject matter and the claimed invention were commonly owned by the same person or subject to an obligation of assignment to the same person at the time the claimed invention was made.

(i) Subject matter developed by another person and a claimed invention shall be deemed to have been commonly owned by the same person or subject to an obligation of assignment to the same person in any application and in any patent granted on or after December 10, 2004, if:

(A) The claimed invention and the subject matter was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made.

However, in the present situation, the subject matter of the Rens et al patent which qualifies as prior art under 35 USC 102(e) has not been disqualified as prior art under 35 USC 103 because it has not been established that the subject matter of the Rens patent and the claimed invention was made by or on behalf of parties to a joint

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research agreement that was in effect on or before the date the claimed invention was made.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634